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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,828	02/17/2004	Sudhir R. Brahmhatt	22-234	9145

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Intellectual Property
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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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07/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/779,828	Applicant(s) BRAHMBHATT, SUDHIR R.	
	Examiner DEBBIE K. WARE	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on BPAI Decision.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6 and 25-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Prosecution is hereby reopened in view of newly discovered references which anticipate some of the claims. Claims 1, 3-6 and 25-26 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Ho et al (US2002/0115132).

The claims are drawn to a fermentation process, the process including the steps of placing a fermentation medium in a vessel, maintaining the fermentation medium in the vessel for a sufficient time to enable a fermentation process to occur in the vessel, and withdrawing a product from the vessel, the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring, wherein the stream of substantially pure oxygen is the sole reactive gas, from any source external to the vessel, that is injected into the vessel, and wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel, and wherein the stream of substantially pure oxygen is moved through the

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vessel solely due to pressure in an oxygen supply. The injecting step can be performed without a blower or compressor or without mixing the oxygen with a liquid.

Ho et al teach a fermentation process wherein commercially pure oxygen 21 having a concentration of 99.5 mole percent is the only gas fed into the vessel 1 containing a fermentation broth through piping 5 from an external source. See (figure 1; paragraph [0019]). Since Ho et al do not teach using a blower or compressor, it is deemed that the oxygen is fed into the vessel under pressure from its source only. Claims 1, 25 and 26 are therefore anticipated by Ho et al.

Claims 1, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Chen et al. Chen et al teach a fermentation process wherein pure oxygen (page 144, column, line 3 from the bottom) fed into a fermenter (see figure 1) from an external oxygen cylinder 4. As shown in figure 4, the oxygen from cylinder 4 is the only gas fed into the fermenter vessel and is fed solely due to pressure in the tank 4. Claims 1, 25 and 26 are therefore anticipated by Chen et al.

Claims 1, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Kubera et al (USP 5972661).

Kubera et al teach a fermentation process wherein a stream of substantially pure oxygen (90-95%) is fed into vessel 10, wherein the stream of substantially pure oxygen is the sole reactive gas (col. 5, lines 42-50), from any source external to the vessel through pipe 50 (figure 1), wherein the stream of substantially pure oxygen is the only

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gas that is injected continuously into the vessel (col. 5, lines 49-50), and wherein the stream of substantially pure oxygen is moved through the vessel solely due to pressure in an oxygen supply (see "self gasification" in claim 2). The injecting step can therefore be performed without a blower or compressor or without mixing the oxygen with a liquid.

It is noted that Kubera et al define substantially pure oxygen as 90-95%. The BPAI relies on the teaching of Cheng B that "pure oxygen" is 99.5 mole percent or more. At the top of page 4 of the Board's Decision, it is stated "Consequently, we interpret 'pure oxygen' as recited in the claims to refer to a gas with an oxygen concentration of 99.5 mole percent or more." (emphasis by examiner). However, the claims recite "substantially pure oxygen". The instant specification does not provide a definition for what "substantially pure oxygen" encompasses. Although there may be an ordinary and customary meaning in the art for "pure oxygen", the examiner was not able to find an ordinary and customary meaning for "substantially pure oxygen". The patents to Bedetti (USP 6692661), Hannaford et al (USP 6482373) and Satchell, Jr. et al (USP 6579085) are cited to show varying percent ranges as definitions for substantially pure oxygen; viz., "no less than 95 molar percent" (Bedetti, column 8, line 42), "at least about 80% by weight" (Hannaford et al, column 2, lines 46-47) and "greater than 70 volume percent, preferably greater than 80 volume percent, more preferably greater than 90 volume percent" (Satchell, Jr. et al, column 5, lines 30-34). Since the instant specification doesn't provide a definition for "substantially pure oxygen" and there doesn't appear to be a standard definition in the art for "substantially pure oxygen", claims 1, 25 and 26 are therefore deemed to be anticipated by Kubera et al.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Ho et al, Chen et al and Kubera et al as applied to claims 1, 25 and 26 above, and further in view of Marwil (USP 4169010). Claims 3-4 set forth that the process further comprises mechanically agitating the fermentation medium and measuring the oxygen concentration and adjusting the flow of oxygen into the vessel in response to the measured concentration of oxygen. Ho et al teaches agitating the fermentation broth by means of an agitator 3 (paragraph 0019, last three lines), but does not teach measuring and adjusting the flow of oxygen. Chen et al teach agitation (page 146, column 1, line 12 to column 2, line 16) and that the oxygen was supplemented automatically and the fermentation was computer controlled and monitored (page 144, column 2, lines 23-29). However, Chen et al do not clearly teach measuring the oxygen concentration and adjusting the oxygen flow in response to the measured oxygen concentration. Kubera et al also teach agitating the medium with impellers 26, 28, 30 and 32, but do not teach the measuring and adjusting steps. Marwil teaches measuring and controlling the stream of substantially pure oxygen (column 2, lines 37-49) fed to a fermentation vessel. The oxygen stream is fed separately in a continuous process for separate control and instrumentation is provided to measure the feed rates (column 8, lines 20-51). It therefore would have been obvious to provide means to measure and control the oxygen flow rates in the processes of Ho et al, Chen et al and Kubera et al in view of Marwil which teaches that it is well known to measure and control oxygen flow rates in a fermentation process.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 25-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 6 of U.S. Patent No. 7,718,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only from each other in the scope of the claimed subject matter.

The patented claims are drawn to a fermentation process, the process including the improvement comprising injecting a stream of substantially pure oxygen into the vessel while the fermentation process is occurring, wherein the stream of substantially pure oxygen is the only gas that is injected continuously into the vessel and is injected external from the vessel or provided outside from the vessel. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the instant claims based upon a reading of the patented claims because the improvement of providing the stream of substantially pure oxygen as the only gas and providing it or producing it to the vessel external from the vessel is clearly taught by the patented claims.

Claims 5-6 are objected to for being dependent upon a rejected base claim and would be allowable over the art of record if made self contained.

All art-rejected claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the art-rejected claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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